



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

PC Codes: 063502, 063503

DP Barcodes: 432572

Date: September 21, 2016

MEMORANDUM

Subject: Registration Review: A Joint Problem Formulation and Draft Risk Assessment of the Environmental Fate and Ecological Risk of Aliphatic Solvents

To: Veronica Dutch, Chemical Review Manager
Jill Bloom, Team Leader
Linda Arrington, Branch Chief
Risk Management and Implementation Branch 5
Pesticide Re-Evaluation Division (7508P)

From: Kristy Crews, Chemist
Stephen Carey, Biologist
Environmental Risk Branch 6
Environmental Fate and Effects Division (7507P)

Through: William Eckel, Ph.D. Senior Science Advisor
Mark Corbin, Branch Chief
Monica Wait, Risk Assessment Process Leader
Environmental Risk Branch 6
Environmental Fate and Effects Division (7507P)

The Environmental Fate and Effects Division has completed the joint problem formulation / draft risk assessment (PF / DRA) for the environmental fate and ecological risk for the registration review of the aliphatic solvents (mineral oil and aliphatic petroleum hydrocarbons; PC Codes 063502 and 063503, respectively).

While new data have not been submitted during the registration review for aliphatic solvents, additional data were not needed to reliably characterize the risk or to change the risk picture from the revised Reregistration Eligibility Decision (RED) in 2007 based on the current use patterns and mode of action. This document serves as an abbreviated registration review assessment by relying primarily on past risk assessments, mainly the EFED RED chapter, and uses current standard models to update potential environmental exposures when applicable.



**Office of Chemical Safety
and Pollution Prevention**

**A Joint Problem Formulation / Draft Risk Assessment of the
Environmental Fate and Ecological Risk in Support of the
Registration Review of Aliphatic Solvents**

**Active Ingredients: Mineral Oil (063502) & Aliphatic Petroleum
Hydrocarbons (063503)**

Prepared by:

Stephen Carey, Biologist
Kristy Crews, Ph. D., Chemist

Reviewed by:

Amy Blankinship, Senior
Andrew Shelby, Physical Scientist
William P. Eckel, Ph. D., Senior Science Advisor
Monica Wait, RAPL
Mark Corbin, ERB6 Chief

***U. S. Environmental Protection Agency
Office of Pesticide Programs
Environmental Fate and Effects Division
Environmental Risk Branch VI
1200 Pennsylvania Ave., NW
Mail Code 7507P
Washington, DC 20460***

September 21, 2016

Contents

1. Executive Summary	4
2. Environmental Fate and Transport.....	9
2.1. Transformation Products	10
3. Receptors and Effects	11
3.1. Effects to Terrestrial and Aquatic Organisms	11
3.2. Ecological Incidents	13
4. Exposure Pathways of Concern	14
5. Analysis Plan	15
5.1. Stressors of Concern.....	15
5.2. Measures of Exposure	15
6. Risk Assessment	17
7. Federally Threatened and Endangered (Listed) Species Concerns.....	19
8. Endocrine Disruptor Screening Program (EDSP).....	20
9. Environmental Fate and Ecological Effects Data	21
9.1. Environmental Fate.....	21
9.2. Effects	21

1. Executive Summary

EFED evaluated the most recent ecological risk assessments for aliphatic solvents in association with the updated toxicity, exposure, and usage information to determine if sufficient data are available and if further updates are needed to support registration review. With no new data submitted and no new significant registration actions since the EFED reregistration eligibility decision (RED) chapter was issued May 15, 2006 (D327645, D313161), EFED proceeded with an abbreviated streamlined risk assessment. For some taxa, EFED will rely largely on the 2006 RED document and with brief summary provided here and details available in the 2006 document. For other taxa, where significant changes in modeling approaches have occurred since the RED, EFED updated those sections using the latest EPA science policies and risk assessment methodologies for those exposure routes and/or taxa. EFED will use application scenarios previously assessed in the EFED RED.

Aliphatic solvents end-use products are formulated as liquid concentrates for use as insecticides and/or larvicides on crops, animal premises, commercial/industrial premises, medical premises, aquatic areas, and residential premises, as well as occupational and residential uses as acaricides, fungicides, herbicides, and virucides (for plant pathogens). When sprayed on plants/premises it is thought that aliphatic solvents products kill the pest by asphyxiating the larvae/organism, rather than direct chemical toxicity. For mineral oil (PC code 063502), there are currently 100 active Section 3 product registrations and 8 special local needs Section 24c registrations. For aliphatic petroleum solvents (PC code 063503), there are currently 19 active Section 3 products.

Aliphatic solvents may be applied at extremely variable rates using diverse methods including foliar spray (ground or aerial), air blast, and direct application to water. At the time of the RED, terrestrial applications rates were as high as 477 lbs a.i./A (pounds of active ingredient per acre). Based on the high variability in the application rates and methods, EFED estimated exposure concentrations of aliphatic solvents to non-target terrestrial and aquatic organisms using a range of labeled application rates (i.e., single applications of 10, 50, 150, and 477 lbs a.i./A using airblast applications). Potential risks to aquatic organisms from direct application to water (37 lbs/A) were also evaluated. Single applications were modeled.

However, the 11/29/2007 revised RED (page 33), states that a required label change coming out of the RED process was to reduce the maximum labeled application rate for citrus from 477 lbs a.i./A to 212 lbs a.i./A (4500 gallons of spray mix/A reduced to a max of 2000 gallons). Implementation of this RED mitigation on active aliphatic solvents product labels is confirmed by the Biological, Economics, and Analysis Division's registration review LUIS report "EFED Label Data Report" dated 8/12/15. The highest maximum application rate listed in that report is 210 lbs a.i./A for citrus, followed by a next highest of 157 lbs a.i./A for olives. Because the EFED RED chapter assessed application rates in bins at 150 and 477 lbs a.i./A, those numbers are carried through into this registration review update. It is important to remember, however, that the currently labeled maximum application rate is 210 lbs a.i./A.

Because single application were modeled, if multiple applications are used at high application rates such that the total amount of aliphatic solvents applied exceeds 477 lbs a.i./A, then risk may

be underestimated in this assessment. In addition, use of repeat applications would likely result in higher longer-term (chronic) average exposure concentrations.

Potential Risks

The risks of aliphatic solvents to terrestrial wildlife and flora exposed to spray uses are summarized in **Table 1** and to aquatic organisms exposed to aliphatic solvents via spray drift alone, runoff alone, and direct application to water are summarized below in **Table 2**. Similar to the 2006 EFED RED Chapter, results of the joint PF and DRA for Registration Review indicate that aliphatic solvents exposures to freshwater invertebrates in waterbodies adjacent to treated fields exceed acute risk levels of concern from spray drift alone, runoff alone, or direct application to waterbodies. A buffer size of 460 feet from the edge of the site reduces the acute risk to freshwater invertebrates from spray drift alone. Estuarine/marine invertebrates also are at acute risk from direct application to water only. Risk to terrestrial and aquatic plants is possible per phytotoxicity warnings on product labels and incident reports of plant damage. Also, there is the possibility of reproduction risk to terrestrial vertebrates that breed on or adjacent to treated fields as Hoffman 2004 reported direct deposition of oils onto eggs in close proximity to the use area would presumably put the eggs at risk because coating of eggs by oils can result in suffocation of the developing bird or mammal.

Acute risks to terrestrial vertebrates, freshwater fish, and adult honey bees are not expected. However, risk concerns cannot be precluded for acute and chronic risks to terrestrial invertebrates, chronic risk to terrestrial and aquatic organisms, and acute risk to estuarine/marine fish due to lack of data.

Table 1. Risk Summary for Terrestrial Wildlife and Flora Exposed to Spray Uses of Aliphatic Solvents ^{1,2}.				
Taxa	Exposure Duration and Endpoint	RQ²	Potential for Risk? / Level of Confidence	Data gaps/ Refinements/ Lines of evidence
Dicot terrestrial plants	Measures of biomass	--	Yes/Low	Terrestrial plants data are not available to evaluate risk. Potential risk presumed based on phytotoxicity warning on labels and plant incidents. However, aliphatic solvents are used on many crops.
Monocot terrestrial plants	Measures of biomass	--	Yes/Low	
Mammals	Acute: Mortality	Not calculated ³	No/High	Reproduction data with terrestrial vertebrates are not available to evaluate risk. Potential risk presumed based on inadvertent oiling of wildlife eggs.
	Chronic: Reproduction	--	Yes/Low	
Birds	Acute oral dose: Sub-acute dietary: Mortality	Not calculated	No/High	
	Chronic: Reproduction	--	Yes/Low	
Terrestrial invertebrates	Individual survival (acute): Adult mortality	Not calculated	No/High	Tier 1 larval acute and chronic larval and adult

	Individual survival (chronic): Adult dietary	--	No data	honey bee chronic data are not available to evaluate risk.
	Brood size and success: Acute and chronic larval	--	No data	

RQ= risk quotient

¹ 'Taxa' cells and 'potential for direct effects' cells are described as follows:

- Yes/High indicates high confidence in a high likelihood of direct adverse effects (e.g., multiple lines of evidence, RQs exceed LOCs, RQs based on reliable data and exposure estimate);
- Yes or No/Low (or no data) indicates lower confidence in a high likelihood of direct adverse effects (e.g., low confidence in data used to calculate RQs, lack of data, or few lines of evidence support the conclusion); and
- No/High indicates a high confidence in a low likelihood of direct adverse effects (e.g., full data set, high confidence in exposure estimates and toxicity dataset).

² The RQ range reflects the RQs for the range of exposure estimates for maximum labeled application rates.

³ RQs were not calculated due to non-definitive toxicity values as no effects occurred at the maximum test concentration or at the solubility limit concentration, the potential for risk is presumed to be minimal.

⁴ Bolded values indicate the non-listed species LOC of 0.5 is exceeded.

Table 2. Risk Summary for Aquatic Organisms and Flora Exposed to Aliphatic Solvents via Spray Drift Alone, Runoff Alone, and Direct Application to Water. ^{1,2}

Taxa	Exposure Duration and Endpoint	Maximum RQ ²	Potential for Risk? / Level of Confidence	Data gaps/ Refinements/ Lines of evidence
Spray Drift Alone (210 lb a.i./A)				
Freshwater fish	Acute: Mortality	Not calculated ³	No/High	Chronic data with aquatic organisms and acute data with the estuarine/marine fish are not available to evaluate risk.
	Chronic: Reproduction	--	No data	
Estuarine / marine fish	Acute: Mortality	--	No data	
	Chronic: Reproduction	--	No data	
Freshwater invertebrates	Acute: Mortality	8.5 ⁴ (No buffer) 0.49 (460 ft buffer size)	Yes/High	
	Chronic: Reproduction	--	No data	
Estuarine / marine invertebrates	Acute: Mortality	0.15	No/High	
	Chronic: Reproduction	--	No data	
Aquatic vascular plants	Frond Count	--	Yes/Low	Aquatic plant data are not available to evaluate risk. Potential risk presumed based on phytotoxicity warning on labels and plant damage incidents. However, aliphatic solvents are used in waterbodies.
Aquatic nonvascular plants	Measures of biomass	--	Yes/Low	
Runoff Alone (210 lb a.i./A)				
Freshwater fish	Acute: Mortality	Not calculated	No/High	Chronic data with aquatic organisms and acute data with the estuarine/marine fish are not available to evaluate risk.
	Chronic: Reproduction	--	No data	
Estuarine / marine fish	Acute: Mortality	--	No data	
	Chronic: Reproduction	--	No data	
Freshwater invertebrates	Acute: Mortality	7.5	Yes/High	
	Chronic: Reproduction	--	No data	
Estuarine / marine invertebrates	Acute: Mortality	0.13	No/High	
	Chronic: Reproduction	--	No data	

Aquatic vascular plants	Frond Count	--	Yes/Low	Aquatic plant data are not available to evaluate risk. Potential risk presumed based on phytotoxicity warning on labels and plant damage incidents. However, aliphatic solvents are used in waterbodies.
Aquatic nonvascular plants	Measures of biomass	--	Yes/Low	
Direct Application to Water (37 lb a.i./A)				
Freshwater fish	Acute: Mortality	Not calculated	No/High	Chronic data with aquatic organisms and acute data with the estuarine/marine fish are not available to evaluate risk.
	Chronic: Reproduction	--	No data	
Estuarine / marine fish	Acute: Mortality	--	No data	
	Chronic: Reproduction	--	No data	
Freshwater invertebrates	Acute: Mortality	105	Yes/High	
	Chronic: Reproduction	--	No data	
Estuarine / marine invertebrates	Acute: Mortality	1.8	Yes/High	
	Chronic: Reproduction	--	No data	
Aquatic vascular plants	Frond Count	--	Yes/Low	Aquatic plant data are not available to evaluate risk. Potential risk presumed based on phytotoxicity warning on labels and plant damage incidents. However, aliphatic solvents are used in waterbodies.
Aquatic nonvascular plants	Measures of biomass	--	Yes/Low	

RQ= risk quotient

¹ 'Taxa' cells and 'potential for direct effects' cells are described as follows:

- Yes/High indicates high confidence in a high likelihood of direct adverse effects (e.g., multiple lines of evidence, RQs exceed LOCs, RQs based on reliable data and exposure estimate);
- Yes or No/Low (or no data) indicates lower confidence in a high likelihood of direct adverse effects (e.g., low confidence in data used to calculate RQs, lack of data, or few lines of evidence support the conclusion); and
- No/High indicates a high confidence in a low likelihood of direct adverse effects (e.g., full data set, high confidence in exposure estimates and toxicity dataset).

² RQ of exposure estimates for maximum labeled application rates.

³ RQs were not calculated due to non-definitive toxicity values as no effects occurred at the maximum test concentration or at the solubility limit concentration, the potential for risk is presumed to be minimal.

⁴ Bolded values indicate the non-listed species LOC of 0.5 is exceeded.

Data Gaps and Uncertainties

Aliphatic solvents have registered use patterns for terrestrial, aquatic, greenhouse, indoor and forestry applications. The available environmental fate and ecotoxicity data sets for aliphatic solvents is very limited. There are many data gaps as compared to the typical list of required studies under 40 CFR Part 158. While the studies listed below are technically data gaps for aliphatic solvents, at this time EFED is not recommending to call in these data with the exception of pollinator data. EFED has determined that additional data with fish, invertebrates, birds, and terrestrial and aquatic plants are not needed to reliably characterize the risk or to change the risk picture as it was described in the 2006 RED. With the pollinator risk assessment guidance updated after the RED to assess potential risks to terrestrial invertebrates, required studies with

honey bees are necessary to conduct a complete risk assessment on pollinators. Additional details are provided in **Table 3** below.

Environmental Fate

- Hydrolysis (835.2120)
- Aquatic Photolysis (835.2240)
- Soil Photolysis (835.2410)
- Aerobic Soil (835.4100)
- Anaerobic Soil (835.4200)
- Aerobic Aquatic Metabolism (835.4300)
- Anaerobic Aquatic Metabolism (835.4400)
- Leaching and Adsorption/Desorption (835.1230 and 835.1240)
- Terrestrial Field Dissipation study (835.6100)
- Aquatic Sediment (835.6200)
- Enforcement Analytical method for Water and corresponding independent laboratory validation (ILV) (850.6100)
- Enforcement Analytical Method for Soil and corresponding ILV (850.6100)

Ecological Effects

- Estuarine/marine fish (850.1075)
- Freshwater invertebrate life cycle (850.1300)
- Estuarine/marine invertebrate life cycle (850.1350)
- Freshwater fish early-life stage (850.1400)
- Estuarine/marine fish early-life stage (850.1400)
- Aquatic plant toxicity test using Lemna spp. (850.4400)
- Algal toxicity (850.4500)
- Cyanobacteria (850.4550)
- Avian oral toxicity using passerines (850.2100)
- Avian reproduction using the mallard and northern bobwhite (850.2300)
- Larval honey bee chronic oral (special study)*
- Larval honey bee acute oral (special study)*
- Adult honey bee chronic oral (special study)*
- Adult honey bee acute oral (special study)*
- Semi-field testing for pollinators (special study)*
- Field testing of residues in pollen and nectar (special study)*
- Seedling emergence (850.4100)
- Vegetative vigor (850.4150)

* These honey bee studies are needed to do a complete risk assessment on the potential risk to terrestrial invertebrates.

The environmental fate and ecological effects dataset for aliphatic solvents is sparse. Therefore, in lieu of data, assumptions were necessary for the completion of an ecological risk assessment as outlined in **Table 3**.

Table 3. Effects of Data Limitations on the Risk Assessment of Aliphatic Solvents.	
Problem Formulation Issue	Effect of Issue on Risk Assessment
Twelve CAS numbers representing numerous formulated products are included in this assessment. However, toxicity data were only available for a small subset of substances included in these PC Codes.	Based on the broad descriptions of the CAS numbers outlined in the RED, it appears that the composition of aliphatic solvents (C ₁₅ -C ₅₀) are similar across the two PC Codes. Hence, the toxicological and fate properties may be similar. However, the data are insufficient to definitively support this conclusion.
Aquatic toxicity data are limited.	Although limitations in the aquatic toxicity data exist, EFED believes that the data provides a weight of evidence regarding the toxicity of aliphatic solvents and approximate exposure due to drift and direct applications to water.
Composition of aliphatic solvents is uncertain.	Composition information is particularly important to allow for an estimation of the relative risks of the various aliphatic solvents and potential aquatic exposures and risks from runoff scenarios.
Toxicity studies in aquatic and terrestrial plants, reproduction toxicity data in birds and mammals, chronic studies in aquatic organisms, acute studies with estuarine/marine fish, and special studies with pollinators have not been submitted.	These endpoints cannot be fully evaluated.
Submitted environmental fate data are not available.	Aquatic EECs from runoff are uncertain.

2. Environmental Fate and Transport

Mineral oils and aliphatic petroleum hydrocarbons products have a wide range of chemical components present, and the submitted data on toxicity, and physical and chemical properties are very limited. According to the 2006 EFED RED, the composition of the aliphatic solvents are similar across the two PC codes. Thus, descriptions concerning the environmental fate and transport will require some degree of generalization.

In the RED, these aliphatic solvents were classified as relatively immobile. EPISuite was utilized to estimate K_{oc}. EFED obtained values $\geq 4,910,000$ g/ml for C₁₅-C₅₀ aliphatics included in the two PC codes.. These estimates put C₁₅-C₅₀ aliphatics in the immobile class, according to FAO classification. This is significant because it is expected that most of the components which make up the aliphatic hydrocarbons will be in the high K_{oc} range. High K_{oc} values are indicative of high sorption to organic matter in soil, as well as to foliar surfaces onto which they are sprayed.

A generalized analysis was completed to determine if aliphatic solvents may have an adverse effect on the environment, in regards to the chain length and solubility. **Table 4** depicts the chain length for aliphatic solvents and the corresponding solubility and toxicity. Unfortunately, the

experimental solubility was not available for each chain length. Additionally, there is not a direct correlation between the experimental and the estimated solubilities (K_{ow} and fragment). The solubility from fragments and K_{ow} estimates were obtained from EPISuite and calculated using WATERNT v1.01 and WSKowwin v1.43, respectively. According to EPISuite, the experimental solubility for C_{15} and C_{20} was obtained from Coates, M et al. (1985) and Mackay, D and Shiu, WY (1981), respectively. The toxicity was generated in EPI Suite under Ecosar v1.11 and analyzed at the LC_{50} predicted toxicity for neutral organics. The mysid at 96-hr LC_{50} was the organism with the lowest toxicity.

Table 4. Effects of Chain Length on the Solubility and Toxicity of Aliphatic Solvents included in PC Codes 063502 and 063503.						
Chain Length	K_{ow} Solubility (mg/L)	Fragment Solubility (mg/L)	Experimental Solubility (mg/L)	Toxicity LC_{50} (mg/L)	Organism	Duration
C_{15}	3.26E-03	2.83E-04	7.60E-05	2.64E-05	Mysid	96-hr
C_{20}	8.92E-06	7.77E-07	0.0019	4.22E-08		
C_{25}	2.05E-08	3.53E-07	-	6.31E-11		
C_{30}	5.06E-11	4.23E-07	-	9.06E-14		
C_{35}	1.28E-13	4.93E-07	-	1.27E-16		
C_{40}	3.41E-16	5.63E-07	-	1.73E-19		
C_{50}	2.63E-21	3.53E-07	-	3.11E-25		

The table above demonstrates that the chain length for aliphatic solvents and the corresponding solubility, as well as the toxicity, are inversely proportional. According to the 2007 Revised RED, these compounds are poorly soluble in water and do not contain functional groups that are susceptible to hydrolysis. The possibility for the alkane to dissolve in water, and cause toxicological effects, declines as the chain length increases, but a close look at these values suggests that solubility above the LC_{50} is still possible. These compounds are poorly volatile and may slowly undergo some primary biodegradation, but do not readily undergo rapid mineralization.

2.1. Transformation Products

There is not definitive information available for degradates produced by aliphatic solvents. This is primarily due to petroleum products with pesticide uses being composed of mixtures of various carbon chain lengths and undergoing differential degradation. The expected degradation products are carboxylic acids of shorter chain length than the starting material. Due to their greater solubility and shorter chain length, these acids are likely less toxic than the starting hydrocarbons.

3. Receptors and Effects

In ecological risk assessments, the effects characterization describes the types of effects a pesticide can potentially produce in an animal or plant. This characterization is generally based on registrant-submitted studies that describe acute and chronic effects information for various aquatic and terrestrial animals and plants; however, these data may also be supplemented by data reported in ECOTOX that have met Agency criteria for acceptability.

Toxicity data reported in this section does not include all species potentially affected by aliphatic solvents use. Only a few species for fish, aquatic invertebrates and birds are used to represent all species in aliphatic solvent use areas. For mammals, toxicity studies are limited for the laboratory rat. Also, neither reptiles nor amphibians are tested. The risk assessment assumes that estimates of risks to avian species are protective of reptilian and terrestrial-phase amphibians. The same assumption is used for fish and aquatic-phase amphibians. Terrestrial plant data are derived from the vegetative vigor and seedling emergence tests, typically on 10 agricultural crop species. Typically, one vascular aquatic plant (*Lemna gibba*) and four aquatic nonvascular plant species are used to represent potential toxicity to all aquatic plant taxa. These studies provide the effects basis for risk estimation. However, as discussed previously in **Table 3**, not all toxicity data were available and assumptions were made in lieu of data.

Tables 5 and 6 provide summary of the available aquatic and terrestrial toxicity data used to characterize the potential ecological effects of aliphatic solvents.

3.1. Effects to Terrestrial and Aquatic Organisms

The Agency previously attempted a more quantitative ecological risk assessment for aliphatic solvents during reregistration. However, toxicity data were not available on all of the mixtures of chain lengths or surrogate species. However, based on the broad descriptions of aliphatic solvents, the composition of the aliphatic solvents that have been tested in the available toxicity studies may be representative of the aliphatic solvents group. **Tables 5 and 6** summarize the aquatic and terrestrial toxicity values used in the ecological risk assessment, respectively. A more detailed toxicity profile can be found in the appendix.

No chronic toxicity studies have been submitted to EFED for use in the risk assessment, and no plant toxicity studies have been submitted to the Agency.

Two acute toxicity studies with mysid shrimps were not included in the 2006 EFED RED; a provisional review of the mysid studies was performed for this risk assessment.

Table 5. Summary of Aquatic Toxicity Values Used in the Aliphatic Solvents Ecological Risk Assessment			
Surrogate Species	Acute Toxicity Value Used	Comment	Data Source
Fish	None Used (All were 'greater than' non-definitive values)	No effects were observed in multiple studies at the limit concentrations for these types of studies.	Weight of evidence was used to estimate potential risks.
Daphnia	0.02 mg/L	LC ₅₀ s were 0.02, 0.1, <0.9, 0.41, and 2.4 mg/L. The lowest value of 0.02 was used in risk estimation	41902803
Mysids	1.15 mg/L	LC ₅₀ : 1.15 mg/L	44625402
Aquatic Plants	No data	None	N/A

Multiple 96-hour acute studies in various fish species have been submitted, but no individual study has been considered adequate for risk estimation. This decision is due to the low solubility of the aliphatic solvents and the lack of analytical confirmation of the test solutions. Though, the data does suggest that loading of the aliphatic solvents at levels that approximate the limit concentration for acute fish toxicity studies (100 mg/L) is not expected to cause mortality in fish.

No daphnid study alone was considered for risk assessment purposes. Due to consistency in the results, EFED believes the 48-hour EC₅₀ in daphnids is likely less than 1 mg/L with the lowest reported EC₅₀ of 0.02 mg/L. It is uncertain if daphnid toxicity effects were caused by physical effects resulting from coating the organism or from a different mode of action.

A submitted study in Eastern oysters suggests that aliphatic solvents are moderately toxic to estuarine/marine invertebrates. This is supported by the acute toxicity study with mysid shrimps (MRID 44625402) exposed to aliphatic solvents. The mysid shrimp study obtained an LC₅₀ of 1.15 mg/L, which is evidence to support that the aliphatics are moderately toxic to estuarine/marine invertebrates. In addition, this study indicates that mysid shrimp are more sensitive than oysters, the mysid LC₅₀ will be used to update potential risk to estuarine/marine invertebrates in this risk assessment. The second study with mysids (MRID 45051302) resulted in a LC₅₀ of >500,000 mg/L.

Table 6. Summary of Terrestrial Toxicity Values Used in the Aliphatic Solvents Screening Level Ecological Risk Assessment			
Surrogate Species	Acute Toxicity Value Used	Comment	Data Source
Birds	None Used	No effects were observed in acute toxicity studies at the maximum concentrations for these types of studies.	Multiple sources used in a weight of evidence approach to estimate potential risks.

Table 6. Summary of Terrestrial Toxicity Values Used in the Aliphatic Solvents Screening Level Ecological Risk Assessment

Surrogate Species	Acute Toxicity Value Used	Comment	Data Source
Mammals	(All were 'greater than' non-definitive values)	No effects were observed in acute toxicity studies at the maximum concentrations for these types of studies.	Weight of evidence was used to estimate potential risks.
Bees		No effects were observed in adult honey bee oral and contact toxicity studies.	Weight of evidence was used to estimate potential risks.
Terrestrial Plants	No data	None	N/A

3.2. Ecological Incidents

The ecological incident information system (EIIS) is an OPP database that houses ecological incidents that have been reported to the Agency. When available, EIIS includes date and location of an incident, type and magnitude of effects observed in various species, use(s) of pesticides known or suspected of contributing to the incident, and results of any chemical residue analysis or other analyses conducted during incident investigation. EIIS incidents are categorized according to the certainty that the incident resulted from pesticide exposure. The Avian Monitoring System (AIMS) is a database administered by the American Bird Conservancy that contains publicly available data on reported avian incidents involving pesticides. Many of the incidents listed in this database are also in the EIIS.

As of August 2016, a review of the EIIS database indicates a total of 13 reported ecological incidents associated with the use of aliphatic solvents (**Table 7**). The reported incidents involved damage mainly to terrestrial plants. Of the incidents reported only four were associated with registered uses of aliphatic solvents as a result of spray or direct applications. The cause of the remaining incidents was undetermined.

In addition, there are 41 aggregate incidents totaling 59 species (2 'wildlife-minor', 57 'plant damage-minor', and 0 'Other Non-Target') reported for aliphatic solvents that were reported by the pesticide registrants.

Table 7. Summary of Ecological Incidents Associated with Aliphatic Solvent uses, By Crop.								
Incident #	Species	Response	Exposure	Certainty	Legality	Formulation	Appl. Method	Magnitude
Plants								
<i>Residential</i>								
I024272-272	Unknown plant	Plant damage	Not reported	Possible	Undetermined	Not reported	Not reported	>45% plants
I024071-252	Ornamentals	Plant damage	Treated directly	Possible	Undetermined	Not reported	Spray	>200 plants
I024179-361	Rose	Plant damage	Not reported	Possible	Undetermined	Not reported	Spray	>45% plants
I024179-095	Unknown fruit tree	Mortality	Not reported	Possible	Undetermined	Not reported	Spray	>45% plants
Terrestrial								
<i>Blackberry</i>								
I023931-046	Apple, blackberry, unknown plant	Mortality	Not reported	Possible	Undetermined	Not reported	Not reported	>45% plants
<i>Residential</i>								
I024071-208	Spruce	Plant damage	Treated directly	Possible	Registered Use	Not reported	Spray	14 plants
I024494-043	Unknown plant	Mortality	Treated directly	Possible	Undetermined	Not reported	Spray	>45% plants
Plants								
<i>Agricultural Area</i>								
I009089-001	Cucumber, tomato	Plant Damage	Treated directly	Possible	Registered use	Not reported	Spray	Unknown
<i>Dry Bean</i>								
I023574-056	Dry bean	Plant Damage	Not Reported	Unlikely	Undetermined	O	Post-emerge	100% plants of 180 acres
<i>Home/Tree</i>								
I001278-001	Beech	Mortality	Not reported	Probable	Undetermined	Not reported	Spray	2 trees
I009089-003	Rose	Plant damage	Treated directly	Possible	Registered Use	Not reported	Hand Spray	21 plants
<i>Kiwi</i>								
I016036-022	Kiwifruit	Plant damage	Treated directly	Possible	Registered Use	Not reported	Spray	380 acres
<i>Pear</i>								
I002969-052	Pear	Plant damage	Not reported	Possible	Undetermined	Not reported	Not reported	Not reported

4. Exposure Pathways of Concern

The available toxicity and environmental fate data are limited for the aliphatic solvents; therefore, assumptions were necessary to allow for a completion of an ecological risk assessment. It is assumed that runoff and spray drift are exposure routes considered for aquatic species and dietary and contact (dermal and egg surface) are exposure pathways of concern for terrestrial species. The assessment for potential risks to non-target surrogate aquatic and terrestrial organisms identified for the currently labeled uses of aliphatic solvents (PC Codes

063502 and 063503) was carried out using screening level methodologies. Animal drinking water and inhalation exposure pathways were screened using the SIP (Screening Imbibition Program) and STIR (Screening Tool for Inhalation Risk) screening methods.

5. Analysis Plan

5.1. Stressors of Concern

Ecological Risk Assessment

Aliphatic solvents are considered as the sole stressor of concern for this assessment. Data have not been submitted to determine if the major transformation product of aliphatic solvents (aliphatic acids) are expected to affect the aquatic estimated environmental concentrations (EECs) or affect terrestrial organisms. However, a separate risk assessment has been done on soap salts, which consist of salts of aliphatic carboxylic acids (EPA-HQ-OPP-2008-0519-0030; March 3, 2015 (D425805)).

5.2. Measures of Exposure

Since there has not been new data submissions for aliphatic solvents since the RED, the exposure data used in this assessment is the same as the data referenced in the 2006 RED. EFED used standard available models to evaluate potential exposures to aquatic and terrestrial organisms and/or exposure routes as described at <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-and-databases-used-pesticide-risk-assessment>.

Aquatic Exposure Assessment

An aquatic exposure assessment was carried out using GENEEC 2.0 and AgDRIFT® 2.1.1. With such high K_{oc} values, the contribution to the EEC from runoff is expected to be below 10 ppm from a single application. In order to reduce the EEC at the single application rate to below the most sensitive level of concern (lowest EC_{50} of 0.02 mg/L x non-endangered species LOC of 0.5 = 0.01 mg/L = 10 µg/L = 10 ppb), EFED conducted an analysis of the extent of a spray drift buffer. GENEEC did not suffice as a run-off modeling tool due to solubility and buffer zone limitations. Thus, AgDRIFT is the most useful modeling tool. A Tier 1 orchard air blast AgDRIFT modeling run at an application rate of 150 lbs a.i./Acre was conducted. With a target concentration of 10 ppb, the distance from the nearest water body needs to be at least 272 ft. Though AgDrift is normally used as a spray-drift modeling tool, in this case it has been used as a surrogate modeling tool for run-off because long chain aliphatics have been assumed to lack drift capabilities.

Tables 8 and 9 depict the values used for GENEEC modeling of aliphatic solvents and the corresponding EECs, respectively. A single application at the maximum application rate of 210 lbs. a.i./A was assumed. For this model, all half-lives (hydrolysis, photolysis and aquatic) were considered stable for the aliphatic solvents. Additional information can be found in the Appendix for GENEEC.

Table 8. GENEEC input values for Exposure Assessment of Aliphatic Solvents Included in PC Codes 063502 and 063503.

Rate (lbs. a.i/A)	Soil K_{oc}	Solubility (ppm)	Appl Type (% Drift)	No-Spray (ft.)	Incorp (in.)	Days Until Rain/Runoff
210	4.91E06	100	Vineyard (1.5)	0	0	2

Table 9. GENEEC EECs for Exposure Assessment of Aliphatic Solvents Included in PC Codes 063502 and 063503.

Peak EEC (ppb)	Max 4 Day Avg EEC (ppb)	Max 21 Day Avg EEC (ppb)	Max 60 Day Avg EEC (ppb)	Max 90 Day Avg EEC (ppb)
152.72	64.88	12.84	4.53	3.04

Terrestrial Exposure Assessment

Terrestrial Vertebrates

Terrestrial wildlife exposure estimates are typically calculated for birds and mammals emphasizing dietary uptake of pesticide through residues on vegetative and insect forage items. Exposure was evaluated using EECs generated from a spreadsheet-based screening model (T-REX v.1.5.2) that calculates the food ingestion rates of birds and mammals and the dissipation of a chemical applied to foliar surfaces for single or multiple applications. No changes were made from the 2006 EFED RED.

The Screening Tool for Inhalation Risk (STIR) and the Screening Imbibition Program (SIP) models were not screened in the 2006 EFED RED, thus are presented below for this assessment.

The Screening Tool for Inhalation Risk (STIR v1.0) was used to calculate an upper-bound estimate of wildlife inhalation exposure using aliphatic solvents' vapor pressure and molecular weight for vapor phase exposure as well as the maximum application rate and method of application for spray drift. STIR incorporates results from several toxicity studies including acute oral and inhalation rat toxicity endpoints (rat LD₅₀ >28000 mg/kg-bw; rat inhalation LC₅₀ = 3.9 mg/L) as well as the most sensitive acute oral avian toxicity endpoint (bobwhite LD₅₀ >2250 mg/kg-bw). Based on the results of the STIR model, exposure through inhalation of spray drift or the vapor phase of aliphatic solvents are not determined to be a potential pathway of concern for either avian or mammalian species on an acute exposure basis.

The Screening Imbibition Program (SIP v1.0) was used to calculate an upper-bound estimate of wildlife drinking water exposure using aliphatic solvents' solubility and compared to the most sensitive acute and chronic avian and mammalian toxicity endpoints. Results of the screen indicate drinking water exposure alone is not a concern for birds or mammals on an acute basis. No chronic

data were available to make an estimation of risk for birds and mammals exposed to contaminated drinking water alone; however, SIP indicates that if a 1 mg/kg-bw toxicity value was used as the bird or mammal NOAEL, there would be no chronic risk concern. Since it is unlikely for reproduction studies to be approximately 2,000 times more toxic than the acute value to obtain a NOAEL as low as 1 mg/kg-bw, it is presumed drinking water exposure alone is not a concern for birds or mammals on a chronic exposure basis as well.

Terrestrial Invertebrates

EECs for terrestrial invertebrates (and pollinators) were not previously assessed. EPA's pollinator risk assessment guidance was established after the 2006 EFED RED, which the Agency uses to evaluate the potential risks to terrestrial invertebrates. In this risk assessment, EECs of aliphatic solvents in pollen and nectar resulting from spray treatment were not calculated for honey bee contact and dietary routes of exposure. EECs will be calculated when the complete set of data for honey bees is available.

Terrestrial Plants

Exposure to upland and wetland plants is estimated using the TerrPlant (v1.2.2) screening model. TerrPlant estimates potential exposure from a single application using default assumptions for runoff and spray drift. No changes are made from the 2006 EFED RED chapter.

6. Risk Assessment

Overall, this streamlined registration review assessment has resulted in no changes to the risk conclusions found in the 2006 EFED RED chapter. In short, there were LOC exceedances identified for freshwater and estuarine/marine invertebrates, and no LOC exceedances for freshwater fish. For terrestrial vertebrates, there are no risks identified for birds (surrogates for reptile and terrestrial-phase amphibians) and mammals from acute exposure. Additionally, there are no chronic data for aquatic and terrestrial organisms and no data for terrestrial and aquatic nonvascular plants with which to assess potential risk to these taxa. Thus, the weight of evidence suggests that with sufficient exposure, effects could occur due the physical, rather than chemical, interactions of aliphatic solvents. Furthermore, it is presumed that there may be possible risks for terrestrial invertebrates with sufficient exposure.

With acute data of the mysids previously not included in the 2006 RED and more sensitive than oysters, the updated risk conclusion for estuarine/marine invertebrates remains unchanged for when aliphatic solvents is applied directly to water; however, the updated spray drift alone and runoff alone RQs in this assessment are below the non-listed species LOC of 0.5. This was determined by comparing the AgDRIFT, GENEEC, and direct application to water EECs of 0.17, 0.15, and 2.1 mg/L, respectively, for spray drift alone, runoff alone, and direct application to water to the acute mysid toxicity value of 1.15 mg/L.

As mentioned in the 2006 EFED RED, no reproduction studies in birds and mammals were available for use in risk assessment. Hoffman *et al.*, 2004 and Albers *et al.*, 2003 reported direct

deposition of oils onto eggs in close proximity to the use area would presumably put the eggs at risk because coating of eggs by oils can result in suffocation of the developing bird or mammal. Other open literature data arrived at similar conclusions as those reported of Hoffman. This indicates there is a potential for risk to terrestrial vertebrates that lay eggs on or adjacent to treated fields.

The dataset is incomplete for aliphatic solvents regarding effects to terrestrial invertebrates. There is no indication of risk based on the available acute oral and contact adult honeybee studies. However, since aliphatic solvents are used as an insecticidal and larvicidal pesticide, this indicates there is potential for risk to honey bees, particularly at different life-stages, and for other terrestrial invertebrates. Pollen and nectar residues on off-site plants that are blooming at the time of treatment can in turn be brought back to bee colonies where in-hive bees including young adult and developing brood (*i.e.*, eggs, larvae and pupae) may be exposed. Therefore, exposure at all bee life stages would be expected and may extend for chronic exposures. Without the toxicity studies to evaluate chronic dietary risk to adult honey bees and acute and chronic dietary risk to larval honey bees, EFED cannot quantitatively evaluate the risks to pollinators who may be exposed from pollen and nectar contaminated by either direct spray or spray drift and carried back to the colony by adult foragers. EPA's pollinator risk assessment guidance was recently updated and outlines the strategy for requesting Tier 1, 2, and 3 data for honey bees. These studies are needed for the assessment to evaluate risks to honey bees if the registered uses of aliphatic solvents will result in adverse effects to honey bees or other insect pollinators. The data would allow the Agency better characterize the potential for risk to insects (including beneficial pollinators) from the use of aliphatic solvents.

As reported in **Table 7** above, the EIIS (Ecological Incidents Information System) database indicates incidents of plant damage; however, there is not much submitted data for terrestrial plants. Yet, according to label use directions, high amounts of aliphatic solvents end-use products are intended to be safely applied onto plant foliar surfaces for insecticidal uses. Also, it was reported in the 11/29/2007 revised RED that most registrants have re-formulated their products with reduced amounts of polyaromatic hydrocarbons (PAHs) and increased amounts of Unsulfonated Residues (lower amounts of nitrogen and sulfur in side-chains) to prevent unwanted phytotoxicity in plants, which minimizes the potential risk to terrestrial plants. However, some aliphatic solvents product labels still have phytotoxicity warnings along with new plant damage incidents since the RED, and it is presumed there is a possible risk for terrestrial plants.

7. Federally Threatened and Endangered (Listed) Species Concerns

In November 2013, the EPA, along with the U.S. Fish & Wildlife Service (USFWS), the National Marine Fisheries Service (NMFS) (collectively, the Services), and the U.S. Department of Agriculture (USDA) released a summary of their joint Interim Approaches for assessing risks to listed species from pesticides. The Interim Approaches were developed jointly by the agencies in response to the National Academy of Sciences' (NAS) recommendations and reflect a common approach to risk assessment shared by the agencies as a way of addressing scientific differences between the EPA and the Services. The [NAS report](#) outlines recommendations on specific scientific and technical issues related to the development of pesticide risk assessments that EPA and the Services must conduct in connection with their obligations under the Endangered Species Act (ESA) and FIFRA.

The joint Interim Approaches were released prior to a stakeholder workshop held on November 15, 2013. In addition, the EPA presented the joint Interim Approaches at the December 2013 Pesticide Program Dialogue Committee (PPDC) and State-FIFRA Issues Research and Evaluation Group (SFIREG) meetings, and held a stakeholder workshop in April 2014, allowing additional opportunities for stakeholders to comment on the Interim Approaches. As part of a phased, iterative process for developing the Interim Approaches, the agencies will also consider public comments on the Interim Approaches in connection with the development of upcoming Registration Review decisions. The details of the joint Interim Approaches are contained in the [white paper](#) "Interim Approaches for National-Level Pesticide Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report," dated November 1, 2013.

Given that the agencies are continuing to develop and work toward implementation of the Interim Approaches to assess the potential risks of pesticides to listed species and their designated critical habitat, this preliminary risk assessment for aliphatic solvent does not contain a complete ESA analysis that includes effects determinations for specific listed species or designated critical habitat. Although EPA has not yet completed effects determinations for specific species or habitats, for this preliminary assessment EPA conducted a brief screening-level assessment for all taxa of non-target wildlife and plants that assumes for the sake of the assessment that listed species and designated critical habitats may be present in the vicinity of the application of aliphatic solvent. This screening level assessment will allow EPA to focus its future evaluations on the types of species where the potential for effects exists once the scientific methods being developed by the agencies have been fully vetted. This screening-level risk assessment for aliphatic solvent indicates potential risks of direct effects cannot be precluded for any of the surrogate species considered in this assessment, except for acute effects to fish, birds, and mammals. Listed species of fish, birds, and mammals may also be acutely affected through indirect effects because of the potential for direct effects on listed and non-listed species upon which such species may rely. Potential direct effects to these listed surrogate species from the use of aliphatic solvents may be associated with modification of Primary Constituent Elements (PCEs) of designated critical habitats, where such designations have been made. Once the agencies have fully developed and implemented the scientific methods necessary to complete risk assessments for endangered and threatened (listed) species and their designated critical

habitats, these methods will be applied to subsequent analyses for aliphatic solvent as part of completing this registration review.

8. Endocrine Disruptor Screening Program (EDSP)

As required by FIFRA and the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, subchronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of the joint Problem Formulation/Ecological Risk Assessment for Registration Review (cite)/most recent registration or reregistration decision (cite), EPA reviewed these data and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database. However, as required by FFDCA section 408(p), aliphatic solvents is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a “naturally occurring estrogen, or other such endocrine effects as the Administrator may designate.” The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA section 408(p), the Agency must screen all pesticide chemicals. The Agency has further defined the “universe” of chemicals subject to EDSP, noting that this universe may change over time and may be subject to prioritization based on factors such as physico-chemical properties, the absence of significant human exposure potential, or other information that indicates a low likelihood to interact with the endocrine system.¹ Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. Aliphatic solvents is not among the group of 58 pesticide active ingredients on the initial list to be screened under the EDSP. For further information on the status of the EDSP, the policies and procedures, the list of 67

¹ USEPA. November 2012. Endocrine Disruptor Screening Program: Universe of Chemicals and General Validation Principles. Available online at http://www.epa.gov/endo/pubs/edsp_chemical_universe_and_general_validations_white_paper_11_12.pdf.

chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit our website: <http://www.epa.gov/endo/>.

9. Environmental Fate and Ecological Effects Data

9.1. Environmental Fate

Submitted environmental fate data are not available. New data have not been submitted or requested during the registration review for aliphatic solvents because additional data were not needed to reliably characterize the risk or to change the risk picture from the revised Reregistration Eligibility Decision (RED) in 2007, based on the current use patterns and mode of action.

9.2. Effects

Tables 10 and 11 identify ecological effects studies by MRID that offer data for each guideline requirement, as well as study classifications and whether or not further data are needed in order to support risk assessment.

Table 10. Submitted Aquatic Ecological Effects Data for Aliphatic Solvents.						
OCSPP Guideline	Data Requirement	PC Code	Submitted Studies (MRID)	Study Classifications	Are data needed for risk assessment?	Current Additional Data Need
850.1010	Freshwater invertebrate acute toxicity	063502	41902803	Supplemental	No	--
		063503	(None)	(N/A)		
850.1025 850.1035 850.1045 850.1055	Estuarine/marine invertebrate acute toxicity	063502	(None)	(N/A)	No	--
		063503	44762002 44625402 45051302	Supplemental In review In review		
850.1075	Freshwater fish acute toxicity	063502	41902802 41902801	Supplemental Supplemental	No	--
		063503	41368834	Supplemental		
850.1075	Estuarine/marine fish acute toxicity	063502	No data submitted or no acceptable data		No	These ecological effects data are not available, which is considered a data gap. However, EPA is not requesting the data and will use the available toxicity data and other resources to make conservative assumption of
		063503				
850.1300	Freshwater invertebrate life cycle	063502	No data submitted or no acceptable data		No	
		063503				
850.1350	Estuarine/marine invertebrates life cycle	063502	No data submitted or no acceptable data		No	
		063503				
850.1400	Freshwater fish early-life stage	063502	No data submitted or no acceptable data		No	
		063503				

Table 10. Submitted Aquatic Ecological Effects Data for Aliphatic Solvents.						
OCSP Guideline	Data Requirement	PC Code	Submitted Studies (MRID)	Study Classifications	Are data needed for risk assessment?	Current Additional Data Need
850.1400	Estuarine/marine fish early-life stage	063502	No data submitted or no acceptable data		No	sensitivity for aquatic organisms.
		063503				
850.1500	Fish life cycle	063502	(None)	(N/A)	No	Not triggered per 40 CFR Part 158.
		063503				
850.1735	Benthic invertebrates (acute)	063502	(None)	(N/A)	No	Data are not available, which is considered a data gap. However, EPA is not requesting the data and will use the available toxicity data and other resources to make conservative assumption of sensitivity for benthic organisms.
		063503				
850.1735	Benthic invertebrates (chronic)	063502	(None)	(N/A)	No	
		063503				
850.4400	Aquatic plant Toxicity Test using Lemna spp.	063502	No data submitted or no acceptable data		No	No toxicity data are available, which is considered a data gap. However, EPA is not requesting the data and will use the available toxicity data and other resources to make a conservative assumption of sensitivity for aquatic plants.
		063503				
850.4500	Algal toxicity	063502	No data submitted or no acceptable data		No	
		063503				
850.4550	Cyanobacteria	063502	No data submitted or no acceptable data		No	
		063503				

Table 11. Submitted Terrestrial Ecological Effects Data for Aliphatic Solvents.						
OCSP Guideline	Data Requirement	PC Code	Submitted Studies (MRID)	Study Classifications	Are data needed for risk assessment?	Current Additional Data Need
850.2100	Avian oral toxicity	063502	41793202 45390801 44608001	Acceptable Acceptable Supplemental	No	A passerine acute oral study with aliphatic solvents is not available, which is considered a data gap; however, EPA is not requesting the data and will use the available terrestrial vertebrate toxicity data and Weight-of-Evidence to make a conservative
		063503	(None)	(N/A)		

						assumption of sensitivity for passerines.
850.2200	Avian dietary toxicity	063502	41742101 41742102 45390802	Acceptable Acceptable Acceptable	No	--
		063503	44780903 44780902	Acceptable Acceptable		
850.2300	Avian reproduction	063502	No data submitted or no acceptable data		No	Acceptable avian reproduction studies using the Mallard and Northern Bobwhite are not available, which is considered a data gap. However, EPA is not requesting the data and will use the available terrestrial vertebrate toxicity data and Weight-of-Evidence to make a conservative assumption of sensitivity for birds.
		063503				
Non-guideline	Avian inhalation	063502	(None)	(N/A)	No	--
		063503				
850.3020	Honey bee acute contact toxicity	063502	41793201 44676701	Acceptable Acceptable	No	--
		063503	44683301	Acceptable		
850.3030	Honey bee residue on foliage	063502	(None)		(N/A)	No data is available; however, EPA is not requesting for the data since the bee contact LD ₅₀ was >1830 µg/bee, which is above the 11 µg/bee criterion that triggers the study.
		063503				
850.3040	Field testing for pollinators	063502	No data submitted or no acceptable data		Yes	The complete dataset of bee toxicity data are not available, which is considered a data gap. Aliphatic solvents are used as an insecticide and larvicide. This suggests pollinators and other terrestrial invertebrates may be impacted when exposed. Data is needed to assess the risks to terrestrial
		063503				
Special Study	Larval honey bee chronic oral toxicity	063502	No data submitted or no acceptable data		Yes	
		063503				
Special Study	Adult honey bee chronic oral toxicity	063502	No data submitted or no acceptable data		Yes	
		063503				
Special Study	Larval honey bee acute toxicity	063502	No data submitted or no acceptable data		Yes	
		063503				
		063502			Yes	

Special Study	Adult honey bee acute oral toxicity	063503	No data submitted or no acceptable data		invertebrates when exposed to aliphatic solvents.
Special Study	Field testing of residues in pollen and nectar	063502	No data submitted or no acceptable data	Yes	
		063503			
Special Study	Semi-field testing for pollinators	063502	No data submitted or no acceptable data	Yes	
		063503			
850.4100	Seedling Emergence and Seedling Growth	063502	No data submitted or no acceptable data	No	No toxicity data are available, which is considered a data gap. However, EPA is not requesting the data and will use the available toxicity data and weight-of-evidence to make a conservative assumption of sensitivity for terrestrial plants.
		063503			
850.4150	Vegetative Vigor	063502	No data submitted or no acceptable data	No	
		063503			

References:

Memorandum Describing the Environmental Fate and Effect Division's Ecological Risk Assessment on Aliphatic Oils (PC Codes 063502 and 063503) in Support of Reregistration Eligibility Decision. B. Anderson, S. Carey, M. Corbin. DP Barcodes 327645, 313161. May 15, 2006.

Revised Reregistration Eligibility Decision for Aliphatic Solvents. November 29, 2007.

Appendix of Aliphatic Solvents Data Submissions

Available Ecotoxicity Studies

850.1010 Acute Toxicity to Freshwater Invertebrates

MRID	Citation Reference
41368833	Rausina, G.; Glenn, L. (1983) 48-Hour Aquatic Toxicity Study in Daphnia with 70 Orchard Spray: Lab Project ID: 82-069. Unpublished study prepared by Gulf Life Sciences Center. 31 p.
41368835	Rausina, G.; Glenn, L. (1983) 48-Hour Aquatic Toxicity Study in Daphnia with 100 Paraffine Oil: Lab Project Number: 82-099. Unpublished study prepared by Gulf Life Sciences Center. 30 p.
41902803	Bellantoni, D.; Peter, G. (1991) 90 Neutral Oil: A 48-Hour Flow- through Acute Toxicity Test with the Cladoceran (Daphnia magna): Final Report: Lab Project Number: 203A/101A. Unpublished study prepared by Wildlife International Ltd. 38 p.
44769301	Drottar, K.; Krueger, H. (1999) GB-1111: A 48-Hour Static Acute Toxicity Test with the Cladoceran (Daphnia magna): Final Report: Lab Project Number: 481A-103: 481/083198/DAP-48H1/SUB481. Unpublished study prepared by Wildlife International Ltd. 57 p.

850.1025/ 850.1035 Acute Toxicity to Estuarine/Marine Invertebrates

MRID	Citation Reference
44625402	Drottar, K.; Krueger, H. (1998) GB-1111: A 96-Hour Static Acute Toxicity Test with the Saltwater Mysid (Mysidopsis bahia): Final Report: Lab Project Number: 481A-102: 481/031198/MYS-96H1/SUB41. Unpublished study prepared by Wildlife International Ltd. 57 p.
44762002	Drottar, K.; Krueger, H. (1999) GB-1111: A 96 Hour Shell Deposition Test with the Eastern Oyster (Crassostrea virginica): Final Report: Lab Project Number: 481A-106: 481083198OYSDEPSUB481. Unpublished study prepared by Wildlife International Ltd. 56 p.
45051302	Reid, J. (1997) Acute Toxicity to Petro Canada Lubricants to Rainbow Trout and Mysidopsis bahia: Lab Project Number: TP970016. Unpublished study prepared by BAR Environmental, Inc. 33 p. {OPPTS 850.1075, 850.1035}

850.1075 Acute Toxicity to Freshwater Fish

MRID	Citation Reference
41368834	Rausina, G.; Glenn, L. (1983) 96-Hour Aquatic Toxicity Study in Rainbow Trout and Bluegill Sunfish with 70 Orchard Spray: Lab Project ID: 1045. Unpublished study prepared by Gulf Life Sciences Center. 16 p.
41902801	

	Peters, G. (1991) 90 Neutral Oil: A 96-Hour Static Acute Toxicity Test with Rainbow Trout (<i>Oncorhynchus mykiss</i>): Final Report: Lab Project Number: 203A-105. Unpublished study prepared by Wildlife International Ltd. 37 p.
41902802	Peters, G. (1991) 90 Neutral Oil: A 96-Hour Static Acute Toxicity Test with the Bluegill (<i>Lepomis macrochirus</i>): Final Report: Lab Project Number: 203A/106. Unpublished study prepared by Wildlife International Ltd. 35 p.
44625401	Drottar, K.; Krueger, H. (1998) GB-1111: A 96-Hour Static Acute Toxicity Test with the Bluegill (<i>Lepomis macrochirus</i>): Final Report: Lab Project Number: 481A-101: 481/031198/BLU-96H1/SUB481. Unpublished study prepared by Wildlife International Ltd. 57 p.
44660001	Ward, T.; Boeri, R. (1998) Acute Toxicity of N65DW to the Bluegill Sunfish, <i>Lepomis macrochirus</i> : Lab Project Number: 1565-PC. Unpublished study prepared by T.R. Wilbury Laboratories, Inc. 18 p.
44708201	Drottar, K.; Krueger, H. (1998) GB-1111: A 96-Hour Static Acute Toxicity Test with the Rainbow Trout (<i>Oncorhynchus mykiss</i>): Final Report: Lab Project Number: 481A-104. Unpublished study prepared by Wildlife International Ltd. 56 p.
45051302	Reid, J. (1997) Acute Toxicity to Petro Canada Lubricants to Rainbow Trout and <i>Mysidopsis bahia</i> : Lab Project Number: TP970016. Unpublished study prepared by BAR Environmental, Inc. 33 p. {OPPTS 850.1075, 850.1035}
45051303	Reid, J. (1997) Rainbow Trout Toxicity Test Report (IPAR3): Lab Project Number: 03970559. Unpublished study prepared by BAR Environmental, Inc. 6 p. {OPPTS 850.1075}
850.1075	Acute Toxicity to Estuarine/Marine Fish
MRID	Citation Reference
44762003	Drottar, K.; Krueger, H. (1999) GB-1111: A 96-Hour Static Acute Toxicity Test with the Sheepshead Minnow (<i>Cyprinodon variegatus</i>): Final Report: Lab Project Number: 481A-105: 48108391SHE96H1SUB481. Unpublished study prepared by Wildlife International Ltd. 55 p.
850.2100	Avian Single Dose Oral Toxicity
MRID	Citation Reference
41793202	Campbell, S.; Hoxter, K.; Smith, G. (1990) 90 Neutral Oil: An Acute Oral Toxicity Study with the Northern Bobwhite: Lab Project Number: 203-119. Unpublished study prepared by Wildlife International Ltd. 19 p.
44608001	Gallagher, S.; Grimes, J.; Beavers, J. (1998) An Acute Oral Toxicity Study with the Northern Bobwhite: GB-1111: Lab Project Number: 481-101: 481/022098/QLD.NC/: SUB481. Unpublished study prepared by Wildlife International Ltd. 41 p.
850.2200	Avian Dietary Toxicity

MRID	Citation Reference
41742101	Long, R.; Foster, J.; Hoxter, K.; et al. (1990) 90 Neutral Oil: A Dietary LC50 Study with the Northern Bobwhite: Lab Project Number: 203-117. Unpublished study prepared by Wildlife Inter- national Ltd. 16 p.
41742102	Long, R.; Foster, J.; Hoxter, J.; et al. (1990) 90 Neutral Oil: A Dietary LC50 Study with the Mallard: Lab Project No: 203-118. Unpublished study prepared by Wildlife International Ltd. 16 p.
44608001	Gallagher, S.; Grimes, J.; Beavers, J. (1999) GB-1111: A Dietary LC50 Study with the Northern Bobwhite: Lab Project Number: 481-102. Unpublished study prepared by Wildlife International Ltd. 62 p.
44780902	Gallagher, S.; Grimes, J.; Beavers, J. (1999) GB-1111: A Dietary LC50 Study with the Northern Bobwhite: Lab Project Number: 481-102. Unpublished study prepared by Wildlife International Ltd. 62 p.
44780903	Gallagher, S.; Grimes, J.; Beavers, J. (1999) GB-1111: A Dietary LC50 Study with the Mallard: Lab Project Number: 481-103. Unpublished study prepared by Wildlife International Ltd. 62 p.
44927401	Gallagher, S.; Grimes, J.; Beavers, J. (1999) N65DW: A Dietary Toxicity Study with the Mallard duck: Lab Project Number: 480-101. Unpublished study prepared by Wildlife International Ltd.
45390801	Gallagher, S.; Grimes, J.; Beavers, J. (2001) N65DW: A Dietary LC50 Study with the Northern Bobwhite: Lab Project Number: 480-103. Unpublished study prepared by Wildlife International Ltd.
45390802	Gallagher, S.; Grimes, J.; Beavers, J. (2001) N65DW: A Dietary LC50 Study with the Northern Bobwhite: Lab Project Number: 480-102. Unpublished study prepared by Wildlife International Ltd.
850.3020	Honey bee acute contact toxicity

MRID	Citation Reference
44683301	Hoxter, K.; Palmer, S.; Krueger, H. (1998) GB-1111: An Acute Contact Toxicity Study with the Honey Bee: Final Report: Lab Project Number: 481-104. Unpublished study prepared by Wildlife International, Ltd. 28 p.
41793201	Winter P.A.; Hoxter K; Smith G. (1990) 90 Neutral Oil: An Acute Contact Toxicity Study with the Honey Bee. Lab project Number: 203-116A. Unpublished study prepared by Wildlife International, Ltd.
44676701	R.L. Boeri; Ward T. (1998) Acute Toxicity of N65DW to the Honey Bee, <i>Apis mellifera</i> . Lab project Number: 1566-PC. Unpublished study prepared by T.R. Wilbury Laboratories.

Available Environmental Fate Studies

835.2120 Hydrolysis

MRID	Citation Reference
135802	Swarbrick, R.; Blum, S. (1970) Regulatory Procedures for Analysis of Petroleum Products: I. Investigation of 121.2589(c). (Unpublished study received 1970 under 9F0771; prepared by Esso Research and Engineering Co., submitted by American Petroleum Institute, New York, NY; CDL:098668-A)

835.4100 Aerobic soil metabolism

MRID	Citation Reference
52640	Winston, A.W., Jr.; Ritty, P.M. (1961) What Happens to Phenoxy Herbicides When Applied to a Watershed Area. (Unpublished paper presented at Northeastern Weed Control Conference; Jan 1961; unpublished study received Sep 1, 1965 under unknown admin. no.; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:128127-K)

835.1240 Leach/adsorp/desorption

MRID	Citation Reference
45945301	Balu, K. (2003) Summary of Adsorption/Desorption and Leaching Potential of Horticultural Spray Oils: Lab Project Number: WEI 724.01: 724.01. Unpublished study prepared by Waterborne Environmental, Inc. 531 p.

835.6100 Terrestrial field dissipation

MRID	Citation Reference
68703	Vernetti, J.; Freed, V.H. (1961) Vapor losses of EPTC from soil. Pages 88-89, ~In~Western Weed Control Conference, Research Progress Report, 1961. (Abstract; also~In~unpublished submission received Jun 23, 1977 under 476-2182; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:230714-I)
91670	Mobay Chemical Corporation (1972) Addition No. 3 To Brochure Entitled: Dylox^(R) Biological Performance and Phytotoxicity on Forest Trees. (Compilation; unpublished study, including published data, received Sep 11, 1972 under 3125-278; CDL:007209-A)
114880	Sweet, R.; Feddema, L.; Crabtree, G.; et al. (1958) Longevity of Several Herbicides in Soils. Proc. NE. Weed Control Conf. 12: 17-24. (Also In unpublished submission received Mar 18, 1976 under 464-402; submitted by Dow Chemical U.S.A., Midland, MI; CDL:095213-G)

120279 Mobay Chemical Corp. (1982) Addition to Synopsis of Matacil: The Effects on the Environment: Environmental Chemistry: ?Summary|: Addition No. 2. (Unpublished study received Dec 9, 1982 under 3125-327; CDL:248988-A)

835.6200 Aquatic field dissipation

MRID	Citation Reference
120279	Mobay Chemical Corp. (1982) Addition to Synopsis of Matacil: The Effects on the Environment: Environmental Chemistry: ?Summary : Addition No. 2. (Unpublished study received Dec 9, 1982 under 3125-327; CDL:248988-A)
120280	Sundaram, K. (1981) Distribution, Persistence and Fate of Matacil Formulations in a Stream Ecosystem: File Report No. 21; 80725. (Unpublished study received Dec 9, 1982 under 3125-327; prepared by Canada, Forestry Service, Forest Pest Management Institute, submitted by Mobay Chemical Corp., Kansas City, MO; CDL: 248988-B)

835.6300 Forest field dissipation

MRID	Citation Reference
120281	Sundaram, K. (1981) Distribution, Persistence and Fate of Matacil Formulations in a Forest Ecosystem: File Report No. 20; 80713. (Unpublished study received Dec 9, 1982 under 3125-327; prepared by Canada, Forestry Service, Forest Pest Management Institute, submitted by Mobay Chemical Corp., Kansas City, MO; CDL: 248988-C)
132473	Sundaram, K. (1983) Letter sent to D. Flint dated Aug 24, 1983: Distribution, persistence and fate of aminocarb (Matacil) in a forest ecosystem: ?Submitter 86122. (Unpublished study received Oct 24, 1983 under 3125-327; prepared by Canada, Forestry Service Forest Pest Management Institute, submitted by Mobay Chemical Corp., Kansas City, MO; CDL:251667-A)

840.1100 Droplet size spectrum

MRID	Citation Reference
44100901	Hewitt, A. (1996) Spray Drift Task Force Atomization Droplet Size Spectra for Nozzle and Physical Property Parameter Characterization: Lab Project Number: A92-003. Unpublished study prepared by Spray Search-Daratech Pty. Ltd. 254 p.

840.1200 Drift field evaluation

MRID	Citation Reference

46042801 Esterly, D. (2003) Evaluation of the Potential Exposure Risk Using Default Spray Drift Assumptions for Application of Horticultural Spray Oils. Project Number: WEI/724/01: 724/01. Unpublished study prepared by Environmental Focus, Inc. 165 p.

Appendix of Toxicity Tables from 2006 EFED RED

Table 1. Summary of submitted fish studies for aliphatic oils			
Chemical	CAS RN	LC50	MRID
100 paraffine Oil	64742-54-7	>100 mg/L	41368834 (2 studies)
GB-1111	None	>120 mg/L	44708201; 44762003
90 Neutral Oil	8012-95-1	>100 mg/L	41902801; 41902802
VHVI-4	None	>76 mg/L	44637336
N65DW	None	>500,000 mg/L	44637335; 44660001

Table 2. Summary of submitted aquatic invertebrate studies for aliphatic oils			
Chemical	CAS RN	LC50	MRID
100 paraffine Oil	64742-54-7	0.41 mg/L	41368835
GB-1111	None	0.1 mg/L	44769301
90 Neutral Oil	8012-95-1	0.02 mg/L	41902803
VHVI-4	None	<0.9 mg/L (100% mortality all levels)	44637337
70 Orchard Spray	64742-55-8	2.4 mg/L	41368833

Table 3. Summary of terrestrial toxicity profile for aliphatic oils				
Test Type	Test Substance	Toxicity Value	Comments	MRID
Bird acute oral LD50 (Mallard Duck, Bobwhite Quail)	GB-1111	>2250 mg/kg-bw	Acceptable study. No mortality or signs of toxicity were observed	44608001
	90 Neutral oil			41793202
Bird acute dietary LD50 (Mallard Duck, Bobwhite Quail)	90 Neutral oil and N65DW	>5620 ppm	NOAEC for sublethal effects was 1000 ppm for 90 Neutral oil based on reduced reaction to external stimuli and increased incidence of top picking. No effects were observed in other dietary subacute studies at any concentration.	41742101
	GB-1111			44780903 44780902
Reproductive Toxicity NOAEL (Bobwhite, mallard duck)	No data	Not available	In the absence of data, a risk estimation cannot be performed, and risk cannot be precluded	None
Honey Bee Contact LD50	GB-1111 90 Neutral oil N65DW	>25 ug/bee >100 ug/bee >1830 ug/bee	No treatment-related effects were observed in any of these studies.	44683301 41793201 44676701
Terrestrial Plants	No data	Not available	In the absence of data, a risk estimation cannot be performed, and risk cannot be precluded.	None

Appendix of Aliphatic Solvents GENEEC Run

TO USE A Kd VALUE, PLEASE ENTER IT HERE - NOTE: TO USE A Koc VALUE PLEASE ENTER ZERO (0) ---> 0

PLEASE ENTER THE APPROPRIATE Koc VALUE ---> 4.91E6

THE DISSOLVED PESTICIDE CONCENTRATION IS ALSO REDUCED BY DEGRADATION IN THE FIELD PRIOR TO A RAINFALL/RUNOFF EVENT

THE PROGRAM ASSUMES DEGRADATION BY AEROBIC METABOLISM BETWEEN APPLICATIONS AND FOR TWO DAYS AFTER THE FINAL APPLICATION

(IF STABLE TO AEROBIC SOIL METABOLISM OR IF DATA IS UNAVAILABLE, PLEASE ENTER ZERO (0))

ENTER SOIL AEROBIC METABOLIC HALFLIFE (IN DAYS) ---> 0

SOME PESTICIDE LABELS REQUIRE THAT THE PESTICIDE BE WETTED-IN EITHER THROUGH RAINFALL OR IRRIGATION AT THE TIME OF APPLICATION

IN THIS CASE, RUNOFF TO THE POND IS ASSUMED TO OCCUR IMMEDIATELY RATHER THAN AFTER TWO DAYS

IS THIS PESTICIDE TO BE WETTED-IN ? (Y or N) ---> n

THE DISSOLVED PESTICIDE CONCENTRATION MAY BE INCREASED BY DIRECT DEPOSITION OF SPRAY DRIFT INTO THE POND

THE PROGRAM ASSUMES A TWO HUNDRED AND EIGHT FOOT WIDE POND LOCATED DIRECTLY DOWN WIND FROM THE SPRAY APPLICATION

THE SPRAY DRIFT PERCENTAGE IS BASED UPON THE WIDTH OF THE NO-SPRAY ZONE AND ON THE SPRAY QUALITY (DROPLET SIZE DISTRIBUTION)

ENTER A, B, C or D TO SELECT METHOD OF APPLICATION:

A: AERIAL SPRAY

B: GROUND SPRAY

C: AIRBLAST SPRAY (ORCHARD & VINEYARD)

D: GRANULAR (NON-SPRAY) ---> c

PLEASE ENTER AIRBLAST TYPE (NOTE: BOTH AIRBLAST SELECTIONS INCLUDE A 3x SAFETY FACTOR):

A: ORCHARDS AND DORMANT VINEYARDS
B: FOLIATED VINEYARDS ---> b

SPRAY DRIFT TO THE POND MAY BE REDUCED BY A NO-SPRAY ZONE
LOCATED BETWEEN THE TREATED FIELD AND THE WATER BODY

THE EFED DEFAULT NO-SPRAY ZONE WIDTH IS ZERO (0) UNLESS
REQUIRED BY THE PESTICIDE LABEL

PLEASE ENTER THE WIDTH OF THE NO-SPRAY ZONE (FEET)
(IF THE LABEL DOES NOT REQUIRE A NO-SPRAY ZONE, ENTER ZERO) ---> 0

THE DISSOLVED PESTICIDE CONCENTRATION IN A WATER
BODY CANNOT EXCEED THE SOLUBILITY OF THE CHEMICAL

PLEASE ENTER THE SOLUBILITY (IN PPM) ---> 100

CHRONIC GENERIC EEC VALUES ARE CALCULATED BY SUMMING
THE INDIVIDUAL AQUATIC DEGRADATION RATES (THE AEROBIC
AQUATIC METABOLIC RATE IS ASSUMED TO INCLUDE HYDROLYSIS)

ENTER ANY OR ALL OF THE FOLLOWING WHICH ARE AVAILABLE:

(PLEASE ENTER ZERO (0) FOR ANY WHICH ARE STABLE OR
FOR WHICH VALUES ARE UNAVAILABLE)

AEROBIC AQUATIC METABOLIC HALFLIFE - DAYS (IF UNAVAILABLE,
RECOMMENDED EFED DEFAULT IS 2x AEROBIC SOIL INPUT VALUE) ---> 0

PLEASE ENTER pH 7 HYDROLYSIS HALFLIFE (DAYS) ---> 0

PLEASE ENTER PHOTOLYSIS HALFLIFE (DAYS) ---> 0

RUN No. 1 FOR Aliphatic Solven ON citrus * INPUT VALUES *

RATE (#/AC)	No.APPS	&	SOIL	SOLUBIL	APPL TYPE	NO-SPRAY	INCRP		
ONE(MULT)	INTERVAL	Koc	(PPM)	(%DRIFT)	(FT)	(IN)			

210.000(210.000)	1	1	4910000.0	100.0	VINYAR(1.5)	0.0	0.0	

FIELD AND STANDARD POND HALFLIFE VALUES (DAYS)

 METABOLIC DAYS UNTIL HYDROLYSIS PHOTOLYSIS METABOLIC COMBINED
 (FIELD) RAIN/RUNOFF (POND) (POND-EFF) (POND) (POND)

0.00 2 N/A 0.00- 0.00 0.00 0.00

 GENERIC EECs (IN MICROGRAMS/LITER (PPB)) Version 2.0 Aug 1, 2001

PEAK GEEC	MAX 4 DAY AVG GEEC	MAX 21 DAY AVG GEEC	MAX 60 DAY AVG GEEC	MAX 90 DAY AVG GEEC
152.72	64.88	12.84	4.53	3.04

DO YOU WANT TO DO ANOTHER RUN (Y OR N) --->